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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,511	12/05/2003	Juha Voipio	3501-1077	7857

466 7590 03/07/2007  
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EXAMINER
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MALAMUD, DEBORAH LESLIE

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

<b>Office Action Summary</b>	<b>Application No.</b> 10/727,511	<b>Applicant(s)</b> VOIP IO ET AL.	
	<b>Examiner</b> Deborah Malamud	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 6 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 December 2006 has been entered.
2. Claims 8-13 are cancelled; claims 1-7 are pending.

### ***Specification***

3. The examiner acknowledges the amendments to the specification and the replacement abstract provided by the applicant.

### ***Drawings***

4. The drawings were received on 15 December 2006. These drawings are acceptable.

### ***Claim Objections***

5. Claim 7 is objected to because of the following informalities: the limitation "said respiratory parameter" in line 10 of the claim has no antecedent basis. Examiner

Art Unit: 3766

suggests replacing this with "the monitored end-tidal carbon dioxide and respiration frequency." Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

6. In view of the amendments to the claims, the examiner withdraws the rejection of claims 1-2, 5, 8-9 and 12 under 35 U.S.C. 102(b) as being anticipated by Renirie et al (U.S. 6,141,590); and of claims 1, 3, 8 and 10 as being anticipated by Obel et al (U.S. 5,199,428). The new grounds of rejection are discussed below.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Zabara et al (U.S. 4,702,254). Zabara discloses (col. 5, lines 33-35; lines 49-54) a pulse generator (10) and its associated parts preferably fully implanted, and provided with means (12, 14 and 16) for "varying the various current parameters of the pulse signal. The desired parameters are chosen by applying the electrodes (22 and 24) to the vagus nerve and varying the current parameters until the desired clinical effect is produced." The examiner considers this to be adjusting the central nervous system affecting vagal

Art Unit: 3766

nerve stimulation (VNS) signal induced by a stimulus generator implanted in a patient in need of vagal nerve stimulation. Zabara further discloses (col. 6, lines 40-60) a sensor-feedback system to block an epileptic seizure automatically using the implantable system. The sensor-feedback system uses, for example, sensed respiratory changes. The examiner considers this to be monitoring respiratory parameters that correlate to the VNS intensity and regulating the stimulation intensity of the central nervous system affecting vagal nerve stimulation in response to the respiratory stimulation in order to affect the brain. It is to be noted that epileptic seizures are considered to be abnormal brain-related conditions.

9. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by King et al (U.S. 2004/0210261). King discloses (par. 0005) "techniques for treating effects of sleep apnea with neurostimulation. An implantable medical device delivers neurostimulation to one or more predetermined locations on or within a patient in order to treat effects of sleep apnea, e.g., by modulating autonomic nervous activity. Delivery of neurostimulation at predetermined locations can decrease sympathetic nervous activity and/or increase parasympathetic nervous activity, countering the increased intrinsic sympathetic activity associated with apnea-arousal cycles." The implantable medical device delivers (par. 0006) neurostimulation to peripheral nerves, such as the vagus nerve. The examiner considers this to be treating an abnormal brain-related conditions by adjusting the central nervous system affecting VNS signal induced by a stimulus generator implanted in a patient in need of vagal nerve stimulation. It is to be

Art Unit: 3766

noted that King also discloses (par. 0003) treatment of central sleep apnea (CSA), which is a "neurological condition causing cessation of substantially all respiratory effort during sleep. One common form of central sleep apnea, commonly known as Cheyne-Stokes respiration (CSR), is characterized by a breathing pattern that begins shallow and infrequent and then increases gradually to become abnormally deep and rapid, before fading away completely for a brief period. Breathing may stop altogether for an extended time period, before the next cycle of shallow breathing begins." In one embodiment, IMD (14; par. 0032; Figure 1) "identifies apnea, or identifies the arousal resulting from apnea, and stimulates spinal cord (20) in response to the identification. Lead (14B) includes a sensor 26 that detects a physiological parameter of patient (12) associated with sleep apnea or arousal. IMD identifies apnea or arousal based on the signal conducted from sensor (26) through lead (16B)." Sensor (26) can detect apnea (par. 0034) "based on respiration of patient as detected via changes in the thoracic impedance. In such embodiments, IMD may monitor frequency, depth, pattern, and variability of respiration. Further, in such embodiments, IMD may detect Cheyne-Stokes rhythm (CSR), or may detect cessation of respiration." The examiner considers this to be monitoring respiratory parameters that correlate to the VNS intensity and regulating the stimulation intensity of the central nervous system affecting vagal nerve stimulation in response to the respiratory stimulation in order to affect the brain.

10. Regarding claims 2 and 5, King discloses (par. 0049) an activity monitor (46) that provides information indicating the activity of the patient. Activity can be determined "based on below-threshold heart rate or respiration rate values." The examiner

Art Unit: 3766

considers this to be monitoring the respiration frequency or respiration rate of the patient.

11. Regarding claim 3, King discloses (par. 0035) an embodiment in which "sensor (26) takes the form of an optical or electrochemical sensor to detect the concentration of a gas within the blood. In such embodiments, sensor generates a signal as a function of the concentration of one or both of oxygen and carbon dioxide in the blood of patient. In such embodiments, IMD detects apnea based on a decreased concentration of oxygen and/or an increased concentration of carbon dioxide in the blood of patient." The examiner considers this to be monitoring the CO<sub>2</sub> content.

***Claim Rejections - 35 USC § 103***

12. In view of the amendments to the claims, the examiner withdraws the rejection of claims 4, 6-7, 11 and 13 under 35 U.S.C. 103(a) as being unpatentable over Renirie et al (U.S. 6, 141,590).

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zabara et al (U.S. 4,702,254) or King et al (U.S. 2004/0210261). Zabara and King disclose the claimed invention but do not disclose expressly the monitoring the respiratory parameter with a capnograph. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the monitoring of the respiratory parameter as taught by Zabara or King, with the capnograph, because the applicant has not disclosed the

Art Unit: 3766

use of a capnograph provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the lead-attached sensors as taught by Zabara and King, because these sensors are able to gather respiratory data in order to affect stimulation of the patient, as claimed by the applicant. Therefore, it would have been an obvious matter of design choice to modify King and Zabara to obtain the invention as specified in the claim.

***Allowable Subject Matter***

15. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. Claim 7 is allowed.

***Conclusion***

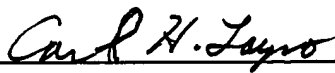
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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